

CLAIMS

1. A sustained release drug delivery device comprising:

- a) a drug core comprising at least one agent effective in obtaining a diagnostic effect or effective in obtaining a desired local or systemic physiological or pharmacological effect;
- b) an impermeable coating layer impermeable to the passage of said agent that surrounds a portion of said drug core;
- c) a suture tab adhered to and extending from said drug delivery device that is used during surgery to adhere said device to the body of a mammalian organism; and
- d) a permeable polymer coating layer, permeable to the passage of said agent that essentially completely covers the impermeable coating layer b) and the uncoated portion of the drug core a) that is not coated with said impermeable coating layer:

wherein the polymer coating layer d) is of a similar polymer material as said suture tab c) and both polymer coating layer and suture tab have been cured at the same time, bonding both together.

2. The sustained release drug delivery device according to Claim 1, wherein said suture tab, when it is first adhered to said drug delivery device, is solid but made of an uncured polymer.

3. The sustained release drug delivery device according to Claim 1, wherein said impermeable coating layer b) is a cup and said drug core a) is a solid that is shaped to be inserted into said cup.

4. The sustained release drug delivery device according to Claim 1, wherein said inner core comprises a plurality of agents.

5. The sustained release drug delivery device according to Claim 1, wherein said inner core comprises an effective amount of a low solubility agent.

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6. The sustained release drug delivery device according to Claim 1, wherein said agent is selected from a group consisting of immune response modifiers, neuroprotectants, corticosteroids, angiostatic steroids, anti-parasitic agents, anti-glaucoma agents, anti-biotics, anti-sense compounds, anti-angiogenic compounds, differentiation modulators, anti-viral agents, anti-cancer agents, and nonsteroidal anti-inflammatory agents.

7. The sustained release drug delivery device according to Claim 1, wherein said impermeable coating layer b) is made of a polymer or a metal.

8. The sustained release drug delivery device according to Claim 7, wherein said impermeable coating layer b) is a cup made of silicone.

9. The sustained release drug delivery device according to Claim 8, wherein said permeable polymer coating layer d) and said suture tab c) are both made of the same polymer material.

10. The sustained release drug delivery device according to Claim 9, wherein said permeable polymer coating layer and said suture tab are both made of PVA.

11. The sustained release drug delivery device according to Claim 1, wherein said suture tab has a hole through the proximal end through which a suture can be placed to anchor the device to a structure of a mammalian body.

12. A method for providing controlled and sustained administration of an agent effective in obtaining a desired local or systemic physiological or pharmacological effect comprising inserting in a desired location in the body of a mammalian organism a sustained release drug delivery device comprising;

a) a drug core comprising at least one agent effective in obtaining a diagnostic effect or effective in obtaining a desired local or systemic physiological or pharmacological effect;

- b) an impermeable coating layer impermeable to the passage of said agent that surrounds a portion of said drug core;
- c) a suture tab adhered to and extending from said drug delivery device that is used during surgery to adhere said device to the body of a mammalian organism; and
- d) a permeable polymer coating layer, permeable to the passage of said agent that essentially completely covers the impermeable coating layer b) and the uncoated portion of the drug core a) that is not coated with said impermeable coating layer:

wherein the polymer coating layer d) is of a similar polymer material as said suture tab c) and both polymer coating layer and suture tab have been cured at the same time, bonding both together.

13. The method according to Claim 12, wherein said inserting step comprises inserting said sustained release drug delivery device in a location selected from the group consisting of the vitreous of the eye, under the retina, and onto the sclera.

14. The method according to Claim 12, wherein said drug core comprises a plurality of agents.

15. A method of manufacturing a sustained release drug delivery device comprising:

- A) providing a drug core comprising at least one agent effective in obtaining a diagnostic effect or effective in obtaining a desired local or systemic physiological or pharmacological effect;
- B) coating a portion of said drug core with an impermeable coating layer impermeable to the passage of said agent;
- C) coating the resulting coated core of B ) with an outer coating of a permeable polymer coating layer, permeable to the passage of said agent that essentially completely covers the impermeable coating layer of B) and the uncoated portion of the drug core of A) that is not coated with said impermeable coating layer; and

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D) curing the resulting device of C) at a temperature of about 130°C to about 160°C for about 1 to about 5 hours;

wherein an uncured solid polymer suture tab has been adhered to the device prior to step D) such that a portion of said suture tab extends away from said device and the curing of step D) jointly cures the uncured solid polymer suture tab and the permeable polymer coating layer of C) and wherein the permeable polymer coating layer applied in C) is of a similar polymer material as said solid polymer suture tab.

16. The method according to Claim 15, further comprising a step between the steps B) and C) of adhering one end of the uncured solid polymer suture tab to the resulting coated core of B).

17. The method according to Claim 15, further comprising a step between the steps A) and B) of adhering one end of the uncured solid polymer suture tab to the uncoated core of A).

18. The method according to Claim 15, further comprising a step between steps C) and D) of drying the resulting coated assembly of C).

19. The method according to Claim 15, wherein the curing step D) dries and cures the resulting coated assembly of C).

20. The method of manufacturing a sustained release drug delivery device according to Claim 15, wherein the coating of step of B) is accomplished by inserting a solid formed drug core of A) into a preformed silicone cup.

21. A sustained release drug delivery device comprising:

1) a coated drug core comprising an inner core comprising at least one agent effective in obtaining a diagnostic effect or effective in obtaining a desired local or systemic physiological or pharmacological effect and a permeable polymer coating layer, the polymer being permeable to the passage of said agent, wherein the permeable polymer coating layer covers at least a portion of the inner core;

2) an impermeable coating layer impermeable to the passage of said agent that surrounds only a portion of said coated drug core; and

3) a suture tab adhered to and extending from said drug delivery device that is used during surgery to adhere said device to the body of a mammalian organism:

wherein the permeable polymer coating layer covering at least a portion of the inner core in 1) is of a similar polymer material as said suture tab 3) and both polymer coating layer and suture tab have been cured at the same time forming a strong bond there between; and wherein said inner core is completely covered by a combination of permeable polymer coating layer, impermeable coating layer, and suture tab such that the agent is able to diffuse out of the inner core through the permeable polymer coating layer or permeable suture tab.

22. The sustained drug delivery device according to Claim 21, wherein said impermeable coating layer of 2) essentially covers the entire coated drug core of 1) and at least one passageway is made through said impermeable layer allowing passage of said agent out of said inner core, through said permeable polymer coating layer, and out of said passageway.

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